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EXAMINER

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ART UNIT PAPER NUMBER

1617

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7

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/077,596

Applicant(s)

SNOW ET AL.

Examiner

Shaojia A Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 1-27 and 42-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-41 and 54-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This application is a continuation in part of 10053625, and is a continuation in part of 09753313, and is a continuation in part of 09938987 which is a continuation of 09079829, which claims priority from Provisional Application 60046672, 60338721, 60339033, 60276866, and 60338969.

However, the parent applications 10053625, 09938987, 09/753,313 and 09079829 upon which priority is claimed, fail to provide adequate support under 35 U.S.C. 112 for the elected invention of Group II claims 32-35 and 54-56 of this application (see Restriction Requirement in the Paper No. 6 and discussed further below).

### ***Election/Restrictions***

Applicant's election of the invention of Group II, Claims 28-41 and 54-56 (drawn to pharmaceutical compositions comprising therapeutically effective amounts of proanthocyanidins and other ingredients herein) in Paper No. 8 submitted July 15, 2003 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Therefore, Claims 1-27, 42-49 and 50-53 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The requirement is therefore made FINAL.

Claims 28-41 and 54-56 are examined on the merits herein.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31, 36-38, 39-41, and 54-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expressions "analogous and derivatives" in claims 31, 36-38 and 56 render claims 31, 36-38 and 56 indefinite. The expressions "analogous and derivatives" is not seen to be clearly defined in the specification as to structure, formula, or chemical name. Hence, one of ordinary skill in the art could not interpret the metes and bounds as to the recitation "analogous and derivatives" in the claim. Therefore, the claims are indefinite as to the composition encompassed thereby.

The term "substantially" in claims 39-41 and 55 is a relative term which renders claims 39-41 and 55 indefinite. The expression "substantially " is not defined in the claim and specification which does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Regarding claim 54, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by

Art Unit: 1617

"or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28-41 and 54-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuznicki et al. (5,681,569, PTO-892).

Kuznicki et al. discloses a composition comprising green tea solids extracted from tea material, i.e., 0.01-0.35% flavanols or catechins wherein the catechin or a mixture of two or more the catechins are catechin, epicatechin, gallocatechin, epigallocatechin gallate and epicatechin gallate (see particularly col.3 lines 20-21 and 26-28), and a pharmaceutical carrier (i.e., water). See also abstract, col.2, lines 12-14; Example I, II, and III at col.10, and claims 1 and 5-6. Thus, the green tea composition of Kuznicki et al. inherently comprises proanthocyanidins oligomers having the formula I and II herein and/or procyanidins such as the dimers and trimers of catechin and epicatechin herein since catechins are known to encompass these compounds which are known to be isolated from green tea.

Kuznicki et al. also discloses the composition therein is therapeutically useful in improving cognitive performance (see col.3 line 33 in particular). The therapeutic

Art Unit: 1617

effective amount of a catechin or mixture of catechins, within the instant claim (10-100mg/kg of body weight of the subject), is disclosed in the Example I and III (see col. 10 lines 1-41) as shown in the calculation below:

Example III discloses that a person can consume 835 cc (835 ml) of a beverage prepared according to Example I (see col.10 lines 40-41).

Since the water in the composition in Example I is 94.45%, the composition is aqueous solution. The density of water = 1 g/ml, thus the total amount of the composition in Example I is 835 g.

According to Example I, the effective amount of catechins (or flavanols)

$$= 835\text{g} \times 0.097\% \text{ (see col.10 line 15 in particular)} = 0.8099 \text{ g} = 809.9 \text{ mg}$$

OR in different calculation, according to Example I (see particularly at col.10 lines 6 and 13-14)

the effective amount of catechins

$$= 835\text{g} \times 0.35/100 \times 29/100 = 0.8475 \text{ g} = 847.5 \text{ mg.}$$

Since a standard person weight is 70 kg, the range of effective amounts of catechins is  $10 \text{ mg/kg} \times 70 \text{ kg} = \underline{700 \text{ mg}}$  to  $1000 \text{ mg/kg} \times 70 \text{ kg} = \underline{70,000 \text{ mg}}$ .

Thus, the effective amount of catechins as exemplified in Example I in the composition of Kuznicki et al., 809.9 mg or 847.5 mg, is within the instant claimed range.

Kuznicki et al. also discloses that catechins therein are extracted from green teas or other plants, and isolated from green tea by methods well known to those in the art

Art Unit: 1617

(see particularly at col.4 lines 6-14). Thus, their percentage purity herein is known to significantly exceed a proportion percentage of the catechin presence in a plant, which is an inherent property of the composition of Kuznicki et al. Kuznicki et al. also discloses that catechins can be prepared by synthetic chemical method or commercially available (see col.4 lines 14-17).

Thus, Kuznicki's composition inherently treat amyloid in a mammal. Moreover, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Thus, Kuznicki et al. anticipates claims 28-41 and 54-56.

Claims 28, 31-41 and 54-56 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 10245342 (PTO-892, of record).

JP 10245342 discloses a pharmaceutical composition for diminishing the toxicity in nerve cells caused by  $\beta$ -amyloid protein comprising a catechin or two or more of catechin such as epigallocatechin gallate and epicatechin gallate prescribed in effective amounts (doses) of diminishing the toxicity of  $\beta$ -amyloid protein (see particularly page 1, the 2<sup>nd</sup> paragraph; claims 1-3 at page 1; page 2 [0001], [0002]), and a pharmaceutical carrier (i.e., water). See also page 7 [0028]; page 8 [0029]. Thus, the green tea composition in JP 10245342 inherently comprises proanthocyanidins oligomers having the formula I and II herein and/or procyanidins such as the dimers and trimers of

Art Unit: 1617

catechin and epicatechin herein since catechins are known to encompass these compounds which are known to be isolated from green tea.

JP 10245342 also discloses that catechins therein are extracted from teas or other plants, and isolated and purified by HPLC (see page 6 [0027]). Thus, their percentage purity herein is known to significantly exceed a proportion percentage of the catechin presence in a plant, and substantially pure isolated, which is an inherent property of the composition therein.

Thus, JP 10245342 anticipates claims 28, 31-41 and 54-56.

Claims 28, 31-41 and 54-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Hashimoto et al. (PTO-892).

Hashimoto et al. discloses a composition comprising or inherently comprising a catechin or two or more of catechins such as epigallocatechin and dimers or proanthocyanidins oligomers having the formula I and II herein and/or procyanidins such as the dimers and trimers of catechin and epicatechin in effective amounts, and a pharmaceutical carrier (i.e., water). See abstract. Thus, the oolong tea composition in Hashimoto et al. inherently comprises the instant compounds herein since these compounds are known to be isolated from oolong tea.

Hashimoto et al. also discloses that catechins therein are extracted from teas or other plants, and isolated (see page 6 [0027]). Thus, their percentage purity herein is known to significantly exceed a proportion percentage of the catechin presence in a



Art Unit: 1617

plant, and substantially pure isolated, which is an inherent property of the composition therein.

Thus, Hashimoto et al. anticipates claims 28, 31-41 and 54-56.

Claims 28, 31-41 and 54-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Hatano et al. (PTO-892).

Hatano et al. discloses a composition for anti-HIV comprising or inherently comprising a catechin or two or more of catechins such as epigallocatechin and dimers or proanthocyanidins oligomers having the formula I and II herein and/or procyanidins such as the dimers and trimers of catechin and epicatechin in effective amounts, and a pharmaceutical carrier (i.e., water). See abstract. Thus, the composition in Hatano et al. inherently comprises the instant compounds herein since these compounds are known to be isolated from Camellia japonica plants. See abstract.

Hatano et al. also discloses that catechins therein are extracted from plants, and isolated (see page 6 [0027]). Thus, their percentage purity herein is known to significantly exceed a proportion percentage of the catechin presence in a plant, and substantially pure isolated, which is an inherent property of the composition therein.

Thus, Hatano et al. anticipates claims 28, 31-41 and 54-56.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

Art Unit: 1617

F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28-41 and 54-56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-15 of the copending Application No. 09/748,748.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending Application is drawn to a drug product containing a composition for treating  $\alpha$ -synuclein fibril formation comprising a compound of Formula E which is epicatechin (see Fig. 1B herein) and a pharmaceutically acceptable excipient. The claim of the instant application is drawn to a pharmaceutical composition comprising epicatechin and a pharmaceutically acceptable excipients of the patent in amounts within the copending Application claim.

Thus, the instant claims are seen to be anticipated by the claims 14-15 of the copending Application No. 09/748,748.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 28-41 and 54-56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 31-39 of the copending Application No. 10/053,625.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending Application is drawn to a pharmaceutical agent comprising or inherently comprising the same compounds herein and a pharmaceutically acceptable excipient. The claim of the instant application is drawn to a pharmaceutical composition comprising the same compounds and a pharmaceutically acceptable excipients of the patent in amounts within the copending Application claim.

Thus, the instant claims are seen to be anticipated by the claims 31-39 of the copending Application No. 10/053,625.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 28-41 and 54-56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,264,994.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a pharmaceutical composition comprising or inherently comprising the same compounds herein and a pharmaceutically acceptable excipient. The claim of the instant application is drawn to a

Art Unit: 1617

pharmaceutical composition comprising the same compounds and a pharmaceutically acceptable excipients of the patent in amounts within the copending Application claim.

Thus, the instant claims 28-41 and 54-56 are seen to be anticipated by the claims 1-18 of U.S. Patent No. 6,264,994.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.



S. Anna Jiang, Ph.D.  
Patent Examiner, AU 1617  
September 25, 2003